Medical Exposures to Ionizing Radiation: Important Developments Since NCRP Report No. 160

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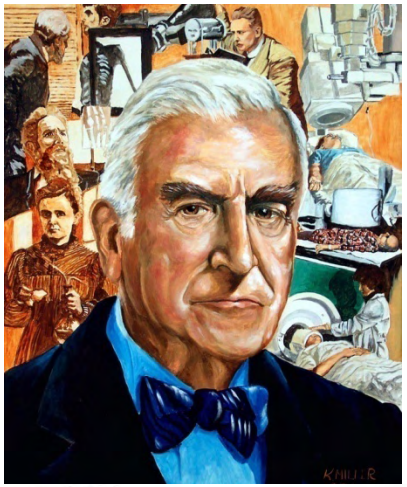
Coeur d'Alene

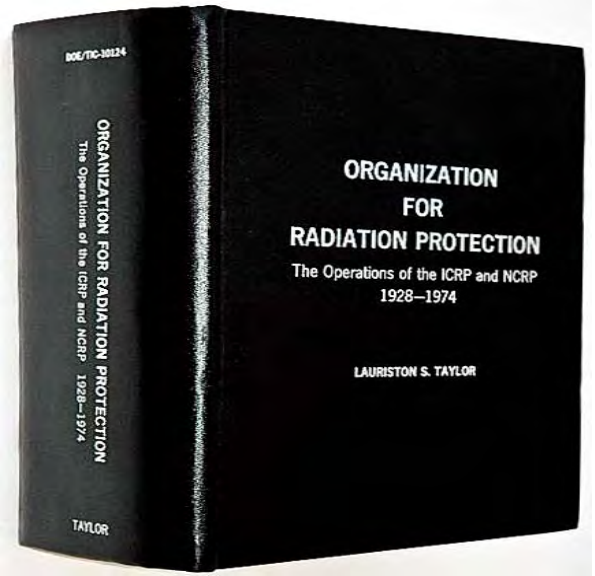
Key Dates in NCRP's History

1929: U.S. Advisory Committee on X-ray and Radium Protection

1946: U.S. National Committee on Radiation Protection

1964: National Council on Radiation Protection and Measurements (NCRP) chartered by U.S. Congress (Public Law 88-376)





Key Elements of NCRP's Charter Under U.S. Public Law 88-376

- **Cornerstones of role in radiation health protection:**
  1. *Collect and analyze* information and recommendations in the public interest about:
     a. protection against radiation; and
     b. radiation measurements, quantities and units.
  2. *Develop* basic concepts of radiation protection;
  3. *Facilitate* effective use of combined resources of organizations concerned with radiation protection; and
  4. *Cooperate* with national and international governmental and private organizations; and
  5. *Disseminate* the Council's work.

Radiation Protection Goals: NCRP Report No. 116

1. prevent the occurrence of clinically significant radiation-induced deterministic effects by adhering to dose limits that are below the apparent threshold levels; and
2. limit the risk of stochastic effects, cancer and genetic effects, to a reasonable level in relation to societal needs, values, benefits gained and economic factors.

Radiation Protection Objectives: NCRP Report No. 116

1. justify any activity which involves radiation exposure on the basis that the expected benefits to society exceed the overall societal cost (justification*);
2. ensure that the total societal detriment from such justifiable activities or practices is maintained ALARA, economic and social factors being taken into account (optimization); and
3. apply individual dose limits to ensure that the procedures of justification and ALARA do not result in individuals or groups of individuals exceeding levels of acceptable risk (limitation).

*Also read NCRP Commentary No. 13, An introduction to efficacy in diagnostic radiology and nuclear medicine (justification of medical radiation exposure)

11th Report on Carcinogens (2004)*

X-Radiation and Gamma Radiation*

Known to be Human Carcinogens

Carcinogenicity

- X-radiation and gamma radiation are *known to be human carcinogens* based on sufficient evidence in humans.
- Epidemiological studies of radiation exposure provide a consistent body of evidence for the carcinogenicity of X-radiation and gamma radiation in humans.
- Exposure to X-radiation and gamma radiation is most strongly associated with leukemia and cancer of the thyroid, breast, and lung; associations have been reported at absorbed doses of less than 0.2 Gy.

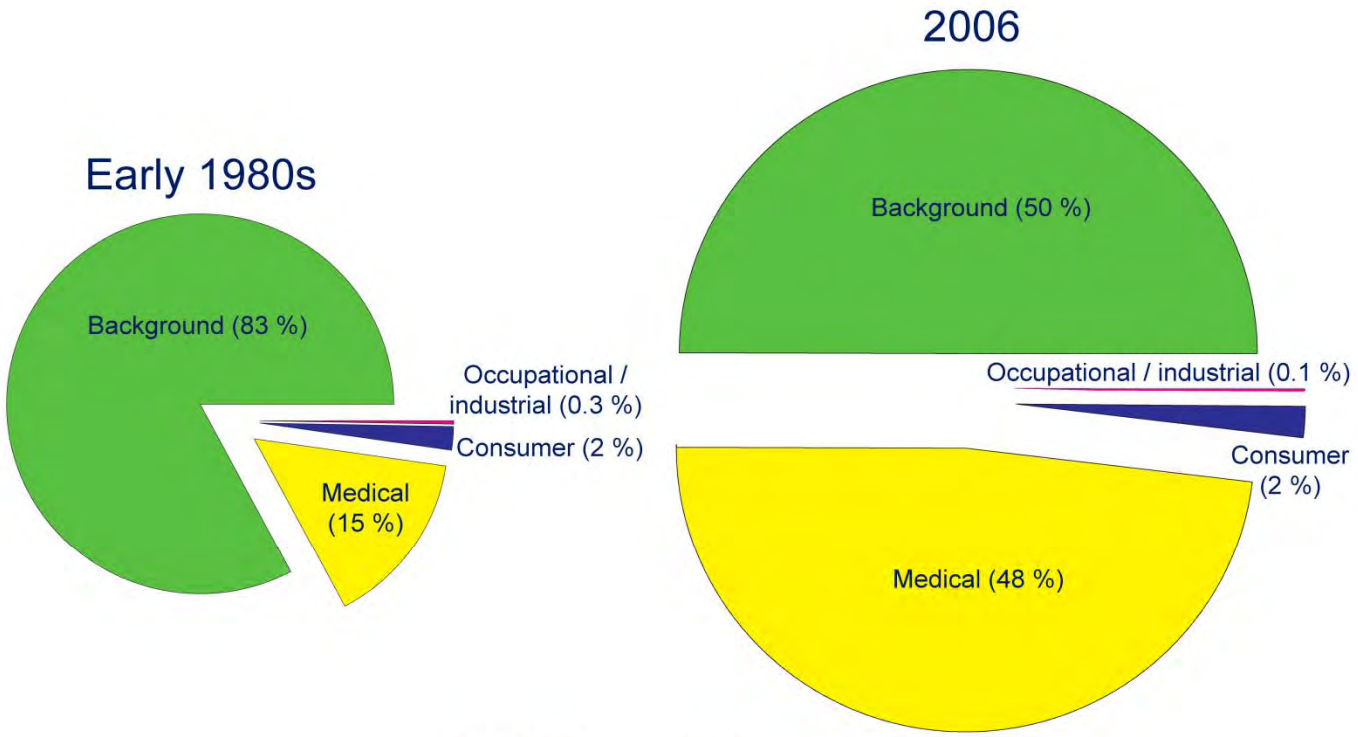
**U.S. Department of Health and Human Services*
Public Health Service
National Toxicology Program
Pursuant to Section 301(b) (4) of the Public Health Service Act as Amended by Section 262, PL 95-622

NCRP REPORT No. 160

IONIZING RADIATION EXPOSURE OF THE POPULATION OF THE UNITED STATES

NCRP 1929 2009

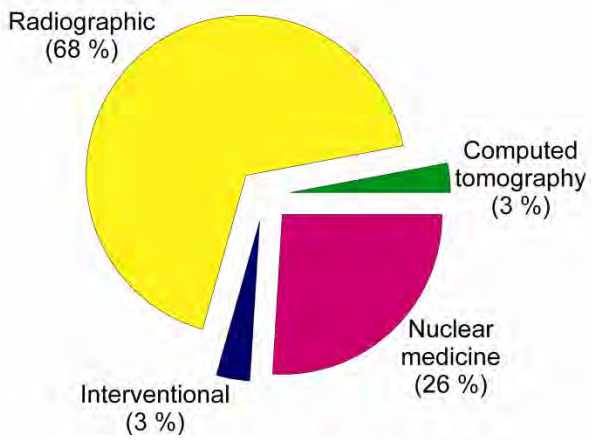
NCRP Report No. 160, *Ionizing Radiation Exposure of the Population of the United States*



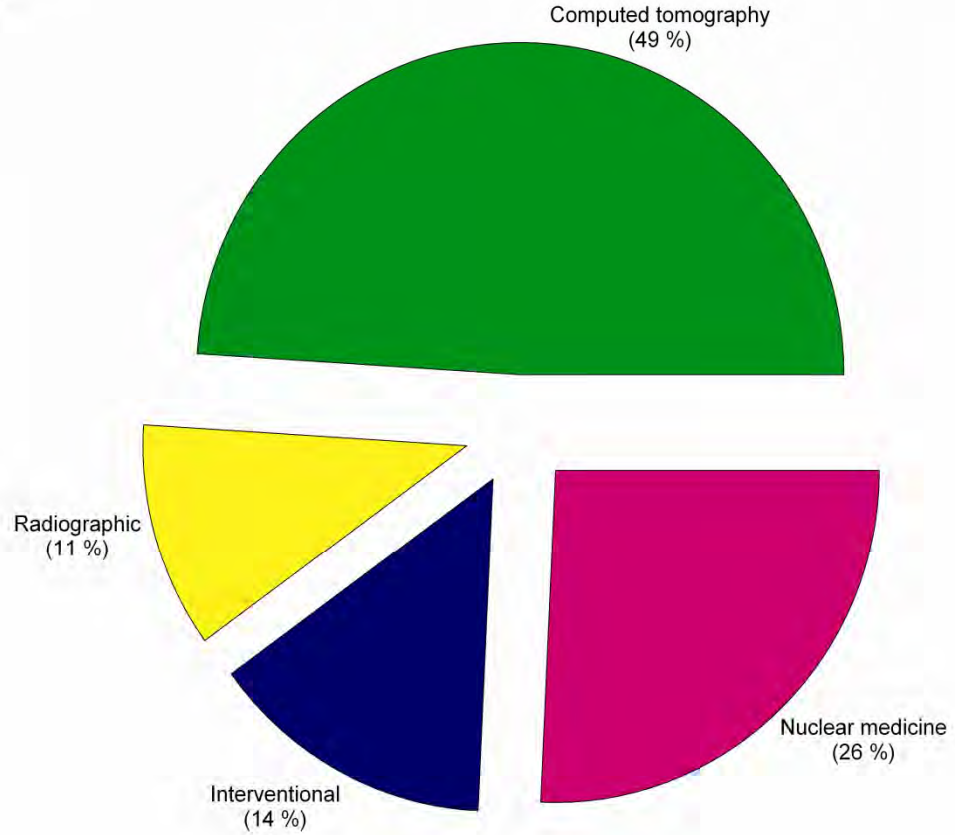
	Early 1980s	2006
Collective effective dose (person-Sv)	835,000	1,870,000
Effective dose per individual in the U.S. population (mSv)	3.6	6.2

NCRP

Medical Exposure of Patients
Collective H_E (percent), early 1980s



Medical Exposure of Patients
S (percent), 2006

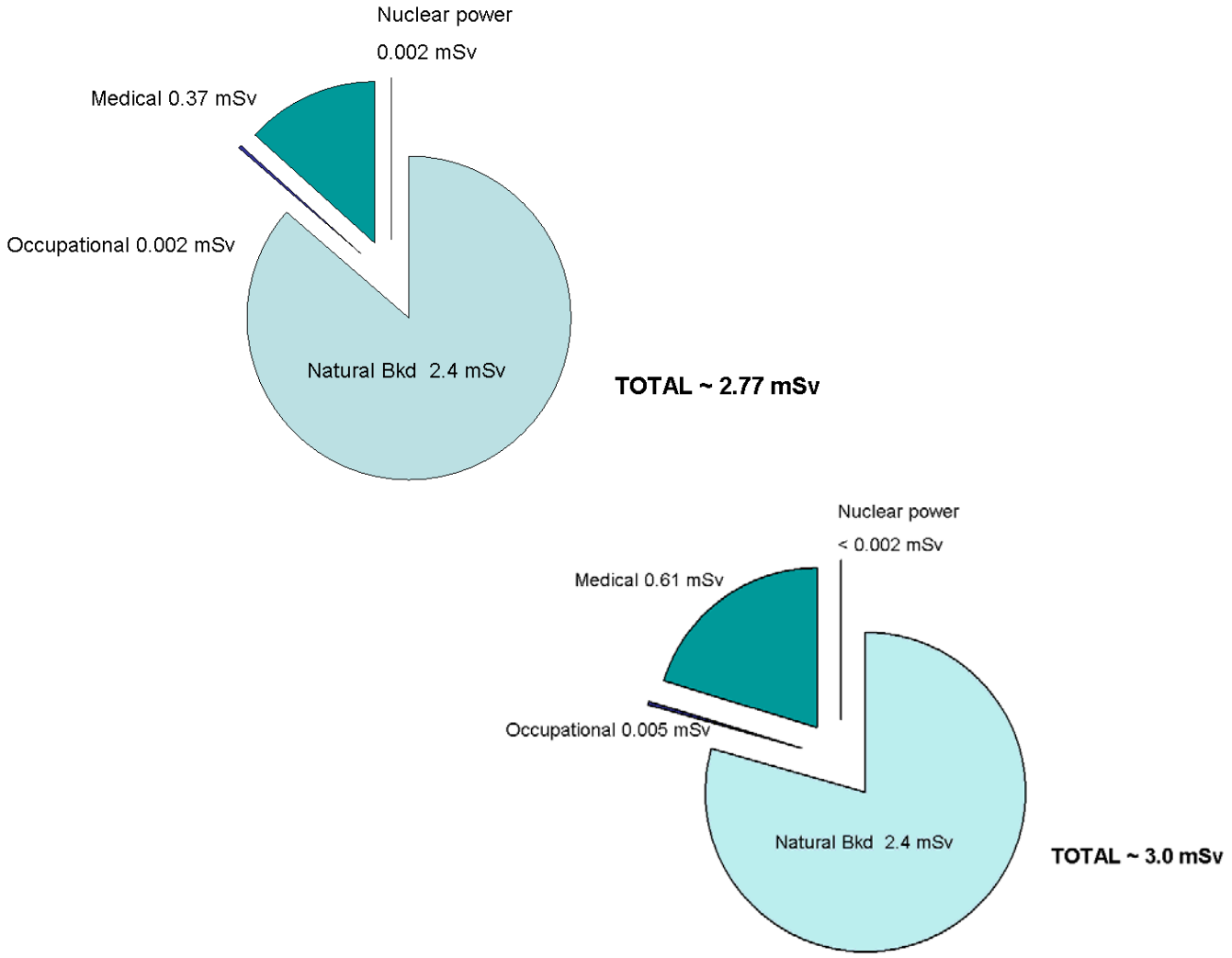


Radiation Exposure to US Population - Medical Exposures

	Number of Procedures (millions)	%	Collective Effective Dose (person Sv)	%	$\underline{E}_{US}$ (mSv)
Computed Tomography	**67**	**17**	**438,000**	**49**	**1.5**
Nuclear Medicine	**18**	**5**	**231,000**	**26**	**0.8**
Interventional	**17**	**4**	**128,000**	**14**	**0.4**
Conventional Radiography & Fluoroscopy	**292**	**74**	**99,000**	**11**	**0.3**
TOTALS	426	100	898,000	100	~3

(600 % increase)

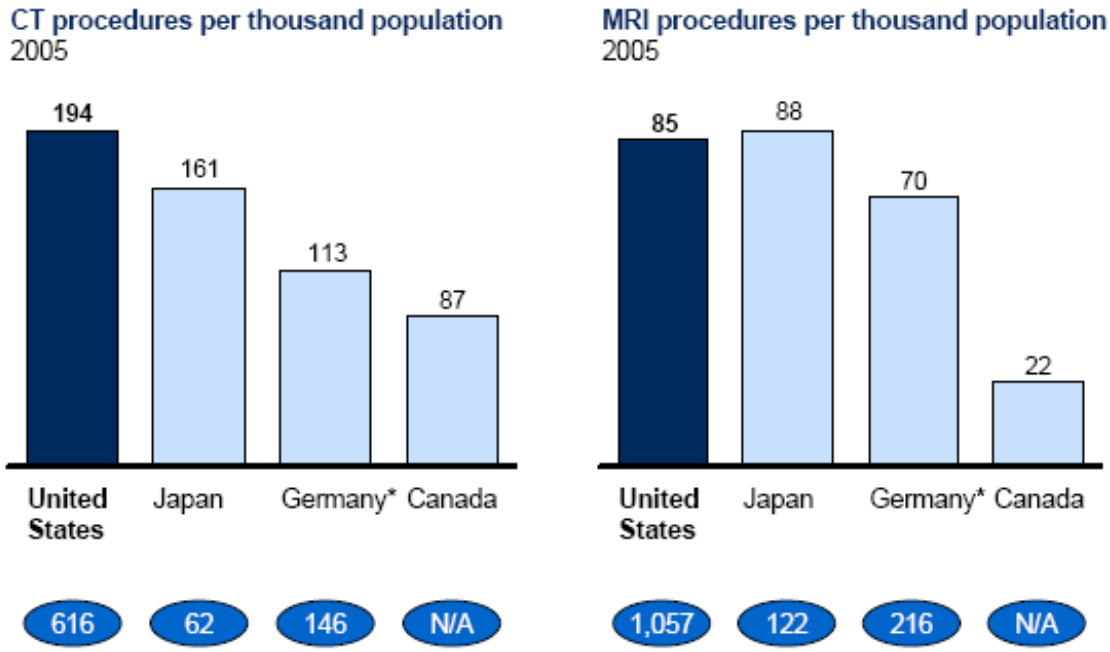
Worldwide View



Global annual per-capita effective radiation dose from various sources for (top) 1980 –1984 and (bottom) 1997–2007

Worldwide View

The United States conducts more diagnostics per capita than other OECD countries and reimburses more favorably



* Data from 2004.

** Reimbursement prices are for 2008 for all countries. All prices are for public reimbursement for an abdominal CT or MRI.

Source: IMV; Japanese Ministry of Health, Labour and Welfare; German Federal Office for Radiation Protection; National Fee Analyzer; EMB; Igakutushin (Japanese medical news agency)

Justification of Medical Exposures

- *How* – use of ACR appropriateness criteria, ACC appropriate use criteria or EU referral guidelines through computerized physician order entry (CPOE);

- Why has this become a significant issue?
  - Supplier-induced Demand (IOM, 2010[#])
    - "If the physician is ordering a study where the payment exceeds the cost, there is a true profit potential. Even in the presence of strong ethical adherence to the Hippocratic oath and similar constructs, the physician may have incentives to over-order imaging studies."
  - Self Referral (GAO report, 2008[*])
    - Physicians who refer patients for imaging in their own office are at least 1.7 to 7.7 times more likely to order imaging than those physicians in the same specialty who do not self-refer.

[#]Value in Health Care – Accounting for Cost, Quality, Safety, Outcomes and Innovation,

[*]GAO-08-452**,** Rapid Spending Growth and Shift to Physician Offices Indicate Need for CMS to Consider Additional Management Practices

Justification of Medical Exposures

- One recent example of what the U.S. Congress is doing about this issue:
  - Anti Self-referral Bill introduced in the House
  - On April 12 Congresswoman Jackie Speier (D-CA) reintroduced to the U.S. House of Representatives the “Integrity in Medicare Advance Diagnostic Imaging Act of 2011” (HR 1476) which seeks to close the in-office ancillary service exception for advanced imaging services such as MR, CT and PET.
  - Upon introduction of HR 1476, Speier stated, “the financial interest of physicians should not be a determining factor in prescribing care for patients. It is terrible to think that this loophole is being abused to enrich doctors while their patients are being unnecessarily exposed to radiation. This bill puts patients first and potentially saves the government billions of dollars in wasteful expenditures.”

Justification of Medical Exposures

- In the absence of direct financial gain, there may be additional payoffs (IOM, 2010)
  - The ordering physician may be able to reduce effort by having a briefer or less intense physical examination.
  - The ordering physician may avoid malpractice costs (real or perceived)
    - Defensive Medicine (Massachusetts Medical Society Report, 2008)
      - Approximately 33 % of CT scans ordered by OB/GYN, EDs and family practitioners were <u>not</u> motivated by medical need.
    - Nearly half of 1,800 emergency physicians reported that the biggest challenge to cutting costs in the emergency department is the fear of lawsuits, according to a poll conducted by the American College of Emergency Physicians (ACEP).
    - In addition, 53 percent of respondents said the main reason they conduct the number of tests they do is the fear of being sued.

Justification of Medical Exposures

- What is being done about this issue by the medical community?
  - "Increasing the Appropriateness of Outpatient Imaging: Effects of a Barrier to Ordering Low-Yield Examinations", Vartanians, *et al*., (June 2010), *Radiology*
  - American Society of Nuclear Cardiology, "Recommendations for Reducing Radiation Exposure in Myocardial Perfusion Imaging", Cerqueira *et al*., (May 2010), *Journal of Nuclear Cardiology*
  - Imaging e-Ordering Coalition
    - require referring physician to enter clinical information (*e.g*., patient's symptoms, known diagnoses, age, *etc*) in a decision support program.
    - processed through an algorithm that relies on ACR's appropriateness criteria to create a decision score.

Optimization of Medical Exposures

- "American College of Radiology White Paper on Radiation Dose in Medicine", *JACR* 4:272-284; (2007)
- Image Gently, Step Lightly and Image Wisely Campaigns
- Medical Imaging and Technology Alliance (MITA)
  - NEMA Standards Publication XR 25-2010 "CT Dose Check" (draft):
    - Notification Value
    - Alert Value

Optimization of Medical Exposures
(AAPM and NEMA XR-25 Standard)

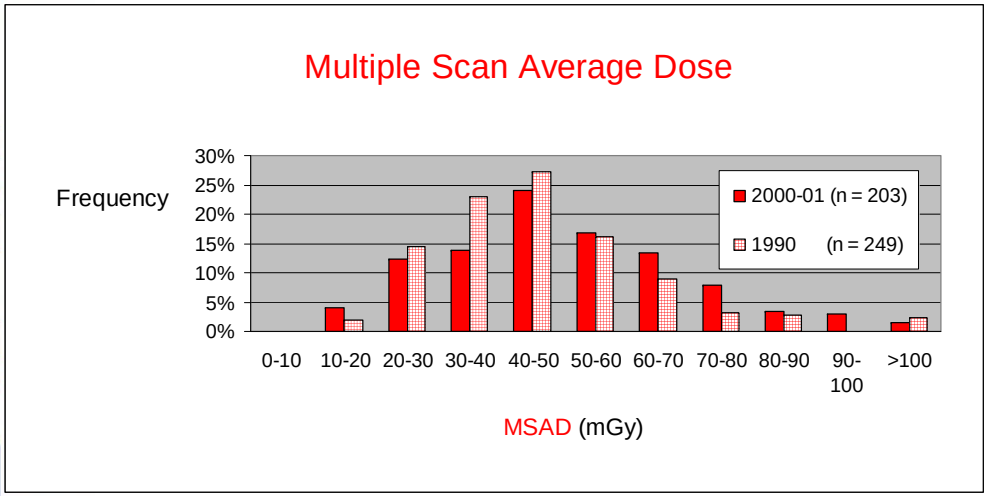
Table 1: Notification Values recommended by the AAPM Working Group on Standardization of CT Nomenclature and Protocols

CT Scan Region (of each individual scan in an examination)	CTDIvol Notification Value (mGy)
Adult Head	80
Adult Torso	50
Pediatric Head	
<2 years old	50
2 – 5 years old	60
Pediatric Torso	
<10 years old (16-cm phantom)[a]	25
<10 years old (32-cm phantom)[b]	10
Brain Perfusion (examination that repeatedly scans the same anatomic level to measure the flow of contrast media through the anatomy)	600
Cardiac	
Retrospectively gated (spiral)	150
Prospectively gated (sequential)	50

An alert warrants more stringent review before proceeding and requires a higher level of action by the user. One purpose of alerting the user is to avoid acute injury, such as erythema or epilation. For this purpose, the FDA has suggested an alert value for *$CTDI_{vol}$ of 1000 mGy,* which would deliver approximately half the dose associated with the onset of skin injury.

Optimization of Medical Exposures

- NCRP scientific committee 4-3, “Diagnostic Reference Levels in Medical Imaging: Recommendations for Application in the United States”



MSAD

	Survey Year 2000-01 (mGy)	Survey Year 1990 (mGy)
mean	50.3	45.9
standard error of sample mean	1.4	1.1
standard deviation	19.4	18.1
n	203	249

“DRLs may be more necessary, because we may be optimizing image quality, and compromising on high patient doses because technology allows us to.” Moore and Iball, Leeds General Infirmary

Putting it All Together (Federal)

- U. S. Food and Drug Administration (FDA)
  Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging

1. Support informed clinical decision making (justification)
   – develop and adopt appropriate use criteria for CT, fluoroscopy, and nuclear medicine procedures
2. Promote safe use of medical imaging devices (optimization)
   – develop nationally recognized diagnostic reference levels for medical imaging procedures that use radiation
3. Increase patient awareness (communication)
   – provide patients with tools to track their personal medical imaging history

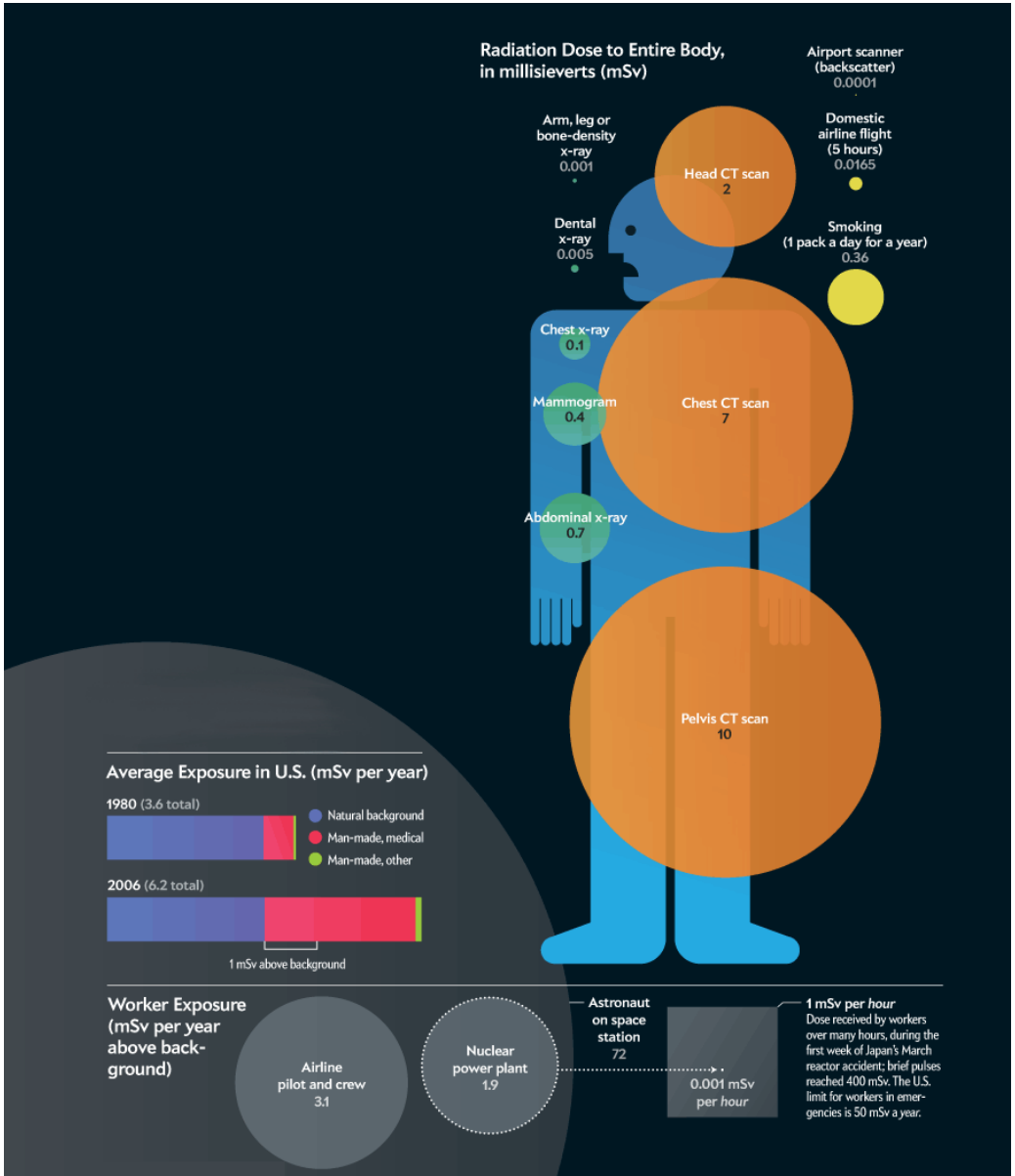
Aim: To help patients get the right imaging exam, at the right time, with the right radiation dose.

Putting it All Together (State)

- The Interim Committee on Public Health recently released a report stating that “increased utilization of imaging equipment has played a major role in the increased amount of healthcare expenditures, especially when imaging equipment owners have been found to over utilize their own equipment.”
- The report goes on to recommend that “the Legislature should require the registration and accreditation of imaging equipment in order to ensure increased transparency and accountability for the operation and use of imaging equipment in Texas.”

http://ethicalimaging,org

Informing a Wider Audience
(Scientific American – May 2011)



Other Topics
(Fukushima and the Media)

An example of the importance of the 27 – 9 – 3 communication rule in a combative environment discussing the potential impact of the Fukushima Daiichi nuclear reactor accident.

Other Topics
(*Radiology* – April 2011)

Does Security Screening with Backscatter X-Rays Do More Good than Harm?[1]

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[1] From the National Council on Radiation Protection and Measurements, 7910 Woodmont Ave, Suite 400, Bethesda, MD 20814-3095. Received December 2, 2010; revision requested December 10; revision received December 15; final version accepted December 19. Address correspondence to the author (e-mail: *schauer@ncrponline.org*).

Potential conflicts of interest are listed at the end of this article.

See also the article by Brenner in this issue.

In 2007, the U.S. Transportation Security Administration (TSA) began to deploy advanced imaging technology (AIT) as a secondary measure to detect threats to air transportation security. This effort was modified (ie, increased in number and used as a primary measure) in early 2010 following the unsuccessful December 2009 attempt by a passenger to blow up a plane with explosive powder. According to the TSA, the AIT technology detects nonmetallic threats, including explosives, weapons, and other concealed objects (1). In an attempt to get a handle on security screening of people with backscatter x-rays, this article will focus on the approach to this issue in the United States. The goals and objectives of radiation protection, however, have worldwide application.

Two types of AIT systems are currently in use by the TSA. One of these systems uses nonionizing radiation in the form of millimeter waves. The other system, which uses backscatter x-rays to create an image, will be discussed in this article.

Backscatter systems use a narrow x-ray beam that scans the subject at high speed from left to right and top to bottom, much like the electron beam inside a television tube. Large detectors on the same side of the subject as the x-ray source detect backscattered radiation, and an image is formed within a few seconds. Most of the radiation detected is scattered near the surface of the skin; hence, the backscatter systems are useful for imaging objects hidden under clothing. They are not useful for detecting objects hidden in body cavities.

Radiologists are knowledgeable about issues related to imaging utilization and radiation effects. In some countries, they are gatekeepers who ensure that medical imaging technologies that expose patients to ionizing radiation are justified (ie, medically appropriate) and optimized (ie, dose is commensurate with the medical purpose). Radiologists are, therefore, the ones to whom patients, airline passengers, and other members of the public are likely to turn with questions about uses of ionizing radiation in medicine and security screening. It is for this reason that the National Council on Radiation Protection and Measurements (NCRP) welcomes the invitation from *Radiology* to discuss the benefits and risks of security screening of people with backscatter x-rays and to consider them in the broader context of other planned exposures (eg, medical radiologic procedures) of people.

The total number of air passengers worldwide was approximately 4.8 billion in 2009 (2). It is unclear what percentage of these passengers should be screened for security purposes. What is known, however, is that the doses will be orders of magnitude smaller than the doses from the 3.6 billion diagnostic radiographic examinations performed worldwide on an annual basis (3).

Overview of Radiation Protection Goals and Objectives

The objectives of radiation protection, as defined in NCRP report 116 (4) and International Commission on Radiological Protection publication 103 (5), are as follows:

1. Justification (ie, to justify any activity that involves radiation exposure on the basis that the expected benefits exceed the overall cost),

2. Optimization (ie, to optimize radiologic protection by ensuring that the likelihood of incurring exposures, the number of people exposed, and the magnitude of their individual doses are all kept as low as reasonably achievable after taking into account economic and societal factors, which includes restrictions on doses or risks to individuals

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  (Chairman, Dr. Toohey, Oak Ridge)

  – March 12-13, 2012 at the Bethesda Hyatt

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